Fred Burbank, MD • Nancy Forcier, MD

Tissue Marking Clip for Stereotactic Breast Biopsy: Initial Placement Accuracy, Long-term Stability, and Usefulness as a Guide for Wire Localization[1]

PURPOSE: To determine initial placement accuracy, long-term stability, and usefulness as a guide for wire localization for metallic marker clips placed percutaneously after stereotactic breast biopsy.

MATERIALS AND METHODS: One hundred forty-nine marker clips were placed percutaneously with a straight-needle or through-probe method, and clip positions were measured. The locations of 31 marker clips were followed up from deployment to first follow-up mammography. Thirty-six biopsy sites with marker clips were excised surgically and examined; 18 of these marker clips were targets for wire localization. The locations of 22 benign lesions were measured over time to calibrate the measurement system.

RESULTS: Baseline variability was 8 mm. Initial marker clip deployment averaged 5 mm above baseline from the center of the target lesion ($P \leq .01$). Compared with baseline variability, marker clips remained in place from initial deployment to first imaging follow-up (mean, 8.6 months). Potentially clinically meaningful misplacement rates (deployment > 24 mm from target lesion center) were 7% for the through-probe method and 11% for the straight-needle method (not significantly different; $P = .33$).

CONCLUSION: The marker clips appear to be useful targets for wire localization when the entire target lesion is removed at directional, vacuum-assisted breast biopsy. Upright, two-view mammography is recommended after deployment of the marker clip to document location.

When percutaneous breast biopsy was first performed with fine-needle aspiration to establish a cytologic diagnosis for a mammographically identified lesion, the concern that fine-needle aspiration would remove the entire target lesion was not addressed, to our knowledge. Conversely, insufficient acquisition of tissue has become the "Achilles' heel" of fine-needle aspiration breast biopsy (1). After the introduction of automated core needle breast biopsy by Parker et al (2) in 1990, concern that a small target lesion might be removed entirely with use of this technique led Dershaw (3) and Sullivan (4) to recommend that automated core needle breast biopsies be performed only on lesions greater than 5 mm in diameter.

Dronkers (5) reported that in six (8.6%) of 70 18-gauge automated core needle breast biopsies (Crown-Core-Cut Needle; Biomed Instrumente Produkte, Turkenfeld, Germany), "... the lesion disappeared after the stereotactic biopsy". Similarly, Mikhail and colleagues (6) reported that in 60 lesions in which breast biopsy was performed with a 14-gauge automated core needle (Biopty-Cut Needle; Bard Gynecology and Radiology, Covington, Ga), three (5%) lesions were malignant and "... were so small that the ... needle biopsy completely removed the focus of malignant cells ...".

An even higher frequency of total excision of all visible target lesion landmarks has been reported after directional, vacuum-assisted breast biopsy. In a study in which 14-gauge directional, vacuum-assisted probes (Mammotome; Biopsys Medical, Irvine, Calif) were used (these probes remove 35–45 mg of tissue per specimen), Burbank reported that 50% of the target lesions could not be identified mammographically immediately after stereotactic breast biopsy and that 48% of the lesions could not be identified at the first imaging follow-up months after the stereotactic biopsy (7,8). Excisional breast biopsies that demonstrate histologically clear margins of atypical ductal hyperplasia, ductal carcinoma in situ, and infiltrating breast cancer for lesions 5 mm in diameter and smaller have been reported in 30% of the 14-gauge directional, vacuum-assisted breast biopsies (9).

Furthermore, directional, vacuum-assisted breast biopsies are now being performed percutaneously with 11-gauge probes. The 11-gauge probe removes approximately 90–100 mg of tissue per specimen (10). At this level of percutaneous removal of breast tissue, all visible signs of the target lesion may be removed at an even higher frequency than reported previously.

When total removal of the target lesion occurs during a diagnostic percutaneous stereotactic breast biopsy and the target lesion proves to be

Index terms: Biopsies, technology, 00.1261, 00.1267 • Breast, biopsy, 00.1261, 00.1267 • Breast neoplasms, diagnosis, 00.31, 00.32 • Stereotaxis, 00.1267

Radiology 1997; 205:407–415

[1] From the Mission Breast Care Center, Mission Medical Tower, 26732 Crown Valley Pkwy, Ste 170, Mission Viejo, CA 92691 (F.B.); and the Woman's Choice Health Pavilion, Irvine Medical Center, Irvine, Calif (N.F.). Received April 21, 1997; revision requested June 16; revision received July 7; accepted July 8. **Address reprint requests to** F.B.

F.B. and N.F. are shareholders in Biopsys Medical.

See also the article by Liberman et al (pp 417–422) in this issue.

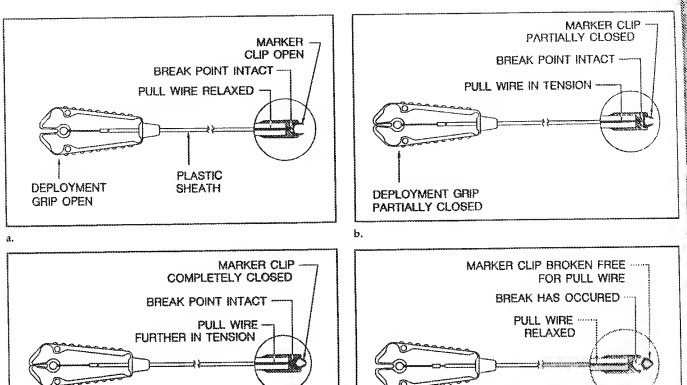


Figure 1. Diagram shows the closure sequence of the marker clip.

atypical ductal hyperplasia, ductal carcinoma in situ, or infiltrating breast cancer, the question remains as to how the biopsy site can be identified accurately for presurgical wire localization. Another question remains as to how the biopsy site can be identified unambiguously during 3 or more years of imaging follow-up when the target lesion proves to be benign.

To address the problem of total removal of a target lesion during directional, vacuum-assisted stereotactic breast biopsy, a 15-gauge, 2 × 2-mm, percutaneous metallic marker clip was developed (MicroMark; Biopsys Medical) and approved by the US Food and Drug Administration on March 15, 1995 for placement in soft tissues. The marker clip and deployment system adds a cost of $75 and approximately 1–2 minutes to the stereotactic breast biopsy procedure.

The purpose of this study was to determine (*a*) the initial accuracy of placement of a marker clip immediately after directional, vacuum-assisted breast biopsies; (*b*) stability of the marker clip after placement from time of insertion to the first follow-up mammographic study; and (*c*) the usefulness of the marker clip as a mammographic guide during wire localization before therapeutic breast surgery.

MATERIALS AND METHODS

A total of 171 patients were studied; 22 patients (average age, 46.8 years; range, 38–85 years) contributed benign control lesions for calibration of the measurement system. In 149 patients (average age, 53.5 years; range, 32–86 years), biopsy was performed with a 14- or 11-gauge directional, vacuum-assisted probe (Biopsys Medical) and marker clips were placed. Between December 8, 1995, and January 28, 1997, 49 (33%) directional, vacuum-assisted biopsies were performed with 14-gauge directional, vacuum-assisted probes and 100 (67%) biopsies were performed with 11-gauge probes. Two radiologists (F.B., N.F.) performed all marker clip placements. The details of performing a directional, vacuum-assisted breast biopsy have been published previously, including complication rates (10,11). Each patient gave informed consent before undergoing biopsy and receiving a marker clip.

Aggregate specimen weights were measured and reported by the attending pathologist at Mission Hospital Regional Medical Center as part of the gross pathologic description for each directional, vacuum-assisted breast biopsy sample. Directional, vacuum-assisted biopsies were categorized as excisional or incisional by examining two ×8 magnified stereotactic digital mammograms and two upright, craniocaudal and mediolateral oblique mammograms obtained after biopsy and marker clip placement. If no residual signs of the target lesion were seen on either of these two sets of mammograms, the biopsy was categorized as excisional. If residual signs of the target lesion were present, the biopsy was categorized as incisional.

Figure 1 shows the percutaneous 2 × 2-mm marker clip and marker clip assembly. The marker clip has two shapes, depending on whether it is open or closed. When open, the marker clip resembles a tiny horseshoe. When closed, the two limbs of the horseshoe are pinched together, forming a diamond shape. The marker clip assembly consists of a deployment grip, a pull wire attached to the deployment grip at one end and attached to the marker clip at the other end, and a plastic sheath that separates the deployment grip from the marker clip. As tension is applied to the pull wire by squeezing the deployment grip, the marker clip changes from the open shape to the closed shape. When breast tissue is trapped between the limbs of the marker clip, the

marker clip is then attached or "clipped" to that tissue similar to the action of a surgical vascular clip. As progressively more tension is applied, the marker clip breaks free from the pull wire. At deployment, the marker clip is free from the deployment assembly and is attached to breast tissue at or near the directional, vacuum-assisted breast biopsy site. For purposes of description, the marker clip deployment sequence is shown as four separate steps. In practice, the process occurs almost instantaneously (one rapid motion).

Two marker clip deployment methods were used in this study. The first marker clip deployment method is referred to as the "straight-needle" method. The second deployment method is referred to as the "through-probe" method.

For the straight-needle deployment method, six steps were necessary: (*a*) a directional, vacuum-assisted biopsy was performed with a 14-gauge probe (43 deployments) (11); (*b*) the directional, vacuum-assisted probe and motorized probe driver were removed from the stereotactic breast biopsy table and set aside; (*c*) a purpose-built needle holder was placed on the stereotactic breast biopsy table (this needle holder was secured to a straight 13-gauge needle with a pointed, bevel-tipped trocar); (*d*) a new set of coordinates was generated by the computer to position the tip of the straight needle at the biopsy site; (*e*) the straight needle with a central trocar was advanced to the biopsy site; and (*f*) the trocar was removed and the percutaneous marker clip assembly was advanced down the shaft of the straight needle, and the marker clip was attached to the wall of the biopsy cavity as shown in Figure 1.

The through-probe deployment method consisted of two steps: (*a*) directional, vacuum-assisted biopsy was performed with a 14-gauge probe (six deployments) or an 11-gauge probe (100 deployments); and (*b*) the marker clip assembly was advanced through the directional, vacuum-assisted probe, and the marker clip was attached to the wall of the biopsy cavity as shown in Figure 1.

To evaluate accuracy of marker clip placement and placement stability over time, a measurement system was needed to describe accurately the location of the marker clip and the target lesion within the breast. The American College of Radiology Breast Imaging and Reporting System contains a breast lesion location system (12). Although this method is suitable for generally defining the location of a lesion within the breast, it is not suitable for describing small differences in the position of two objects that may be close to one another within the breast. Consequently, we developed and tested a new measurement system, the "mask measurement system."

The mask measurement system transfers information from two mammograms to one sheet of clear x-ray film referred to as the "mask." After information is hand-traced from the two mammograms to the mask, the mask contains information from both mammograms. The first mammogram defines the shape of the breast and the location of an object of interest on the mask. The second mammogram is fitted to the mask, and the object of interest on the second mammogram is drawn on the mask. The objects of interest, whose locations are compared on the masks, can be a target lesion and a marker clip (first context, described later), a marker clip at two points in time (second context), or a target lesion at two points in time (third context).

If the position of an object within the breast was identical on two mammograms and if the breast projected to the same location on each mammogram, then two tracings of the objects on the mask would superimpose exactly. In this idealized example, the tracings of the superimposed objects on the mask could be described as exactly "on target." However, a breast never projects as exactly the same shape on any two mammograms. Furthermore, when a marker clip is placed in the breast, it may or may not embed in the desired location. Finally, even if the marker clip is deployed accurately, it may move from one location to another over time. When the tracing of an object is not in the ideal position on the mask, the object is described as "off target." The distance (in millimeters) that an object is off target is measured directly on a mask with a ruler.

The craniocaudal mask describes the distance off target in one projection; the mediolateral oblique mask describes the distance off target in another projection. To combine the information from the craniocaudal and mediolateral oblique mammogram masks, a single, continuous, dependent variable was defined and referred to as the "average distance off target." The average distance off target has three meanings, depending on three contexts.

Initial Accuracy of Marker Clip Deployment

In the first context, the average distance off target of the marker clip with respect to the target lesion immediately after stereotactic directional, vacuum-assisted breast biopsy and deployment of the marker clip was measured by creating a mask of the craniocaudal and mediolateral oblique mammograms obtained before biopsy. The mask for each projection was created by stapling a clear sheet of x-ray film on top of the craniocaudal and mediolateral oblique mammograms obtained before biopsy (Fig 2a). With use of a bright light, the skin line, the nipple, and an outline of the lesion were traced by hand onto the mask with an indelible film marker (Fig 2b). For mass lesions, the lesion borders were traced; for clustered microcalcification lesions, the outermost edges of the cluster were traced. The center of each lesion was marked with a dot.

After directional, vacuum-assisted biopsy was performed, the marker clip was delivered percutaneously at or near the biopsy site by means of the straight-needle (43 deployments) or through-probe (106 deployments) deployment method. Craniocaudal and mediolateral oblique mammograms were obtained immediately after biopsy and marker clip deployment to define the locations of the marker clip within the breast in the craniocaudal and mediolateral oblique projections (Fig 2c). The target lesion was commonly removed entirely, distorted, or obscured as a result of the directional vacuum-assisted biopsy. Consequently, the target lesion was often no longer visible or identifiable on the mammograms obtained after biopsy and marker clip placement. The marker clip, however, was always clearly visible.

Finally, the craniocaudal mask was placed on top of the craniocaudal mammogram obtained after biopsy and marker clip placement, and the mediolateral oblique mask was placed on top of the mediolateral oblique mammogram obtained after biopsy and marker clip placement. The skin outlines from each corresponding mask and mammogram obtained after biopsy were fitted together with use of a bright light and the position of the nipple as the fulcrum to achieve the best overall "fit." Once the fit was optimal, the position of the marker clip was drawn as a diamond on the craniocaudal and mediolateral oblique masks with an indelible marker (Fig 2d).

The craniocaudal and mediolateral oblique masks then contained the locations of the two objects of interest: the target lesion and the marker clip. The distance from the center of the target lesion to the center of the marker clip was measured (in millimeters) on the masks in the craniocaudal and mediolateral oblique projections (Fig 2d). The distances between the target lesion and the marker clip in the craniocaudal and mediolateral oblique projections were averaged: average distance = [(craniocaudal distance + mediolateral oblique distance)/2], creating the average distance off target for the initial deployment of the marker clip. The average distance off target in this context is a measurement of the marker clip distance from the target lesion center. Since two deployment methods were used in this study, the average distance off target was analyzed according to deployment method.

Stability of Marker Clip Placement Over Time

In the second context, the stability of marker clip placement over time was measured by comparing the position of the marker clip on the craniocaudal and mediolateral oblique masks immediately after biopsy and marker clip deployment to the position of the marker clip on craniocaudal and mediolateral oblique mammograms obtained at first imaging follow-up. As before, the skin outlines from the mammograms obtained at first imaging follow-up were fitted to the craniocaudal and mediolateral oblique masks by using the nipple as the fulcrum to create the best fit between each follow-up mammogram first imaging follow-up mammogram and the corresponding mask.

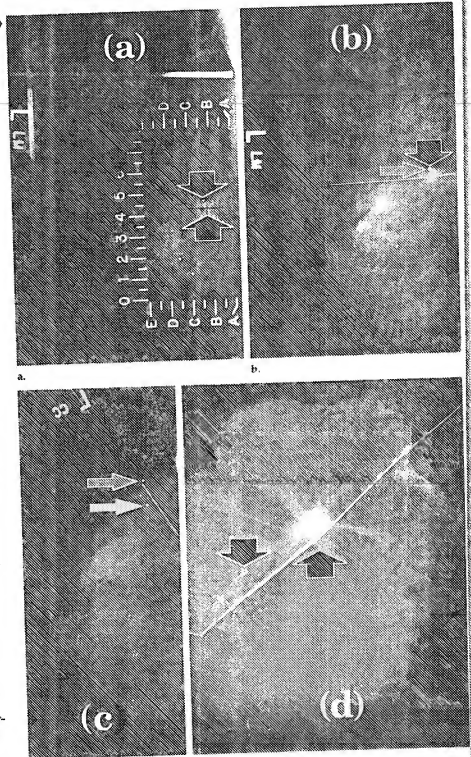


Figure 3. Photographs of mammograms show the steps necessary to use a marker clip as a target for wire localization before surgery. Wire localization was performed in the same lesion shown in Figure 2. (a) Lateromedial mammogram obtained with an alphanumeric grid placed over the left breast in the lateromedial projection. Wax pencil lines have been drawn on the lateromedial mammogram grid over the region of residual target lesion (upward-pointing arrow) just adjacent to the marker clip (downward-pointing arrow). A stiffened localization wire (Kopans Spring Hookwire; Cook, Bloomington, Ind) was then placed where the wax pencil lines cross in the lateromedial projection. (b) Lateromedial mammogram helps verify the position of the localization wire. The black arrow highlights the marker clip; the gray arrow highlights a "BeBe" (Beekley Spots with Pik-Up; Beekley Corporation, Bristol, Conn), which has been placed at the skin entry site of the wire. (c) Craniocaudal mammogram shows the position of the localization wire, the marker clip (white arrow), and the skin BeBe (gray arrow). (d) Magnified (×2) radiograph of the surgical specimen cut and compressed in a plastic transportation and compression container (TranSpec; E-Z-Em, Westbury, NY) shows the residual target lesion (upward-pointing arrow), the marker clip (downward-pointing arrow), and the localization wire. The marker clip has been moved away from the target lesion with surgical transection of the specimen and pressure from the plastic compression container.

Of 149 marker clips placed, 36 (24%) patients subsequently underwent surgical therapy. At stereotactic biopsy, infiltrating breast cancer was diagnosed in 20 (56%) of the 36 lesions, ductal carcinoma in situ in 13 (36%) lesions, and atypical ductal hyperplasia in three (8%) lesions. The type of surgery performed, whether the marker clip was used as a guide for wire localization, whether a radiograph was obtained of the surgical specimen, and the disribution of histologic diagnoses are summarized in Table 4.

In eight (22%) of the 36 lesions, no preoperative wire localization was performed. Seven of the eight surgeries were mastectomies and the other surgery was breast-conserving surgery directed by palpation of a hematoma presumed by the surgeon to be at the directional, vacuum-assisted breast biopsy site. In 10 (28%) of the 36 lesions, the marker clip was used as the target for wire localization. However, no radiograph was obtained of the specimen because the biopsy site was readily visible during surgery and radiography was deemed redundant by the surgeon. In 18 (50%) of the 36 lesions, the marker clip was used as the target for wire localization and a radiograph was obtained of the specimen. On all 18 (100%) of these radiographs, the marker clip and the previous biopsy site were identified positively in the specimen.

In 29 (81%) of the 36 lesions, the biopsy site and residual tumor were identified positively at histopathologic examination. In the remaining seven (19%) lesions, the biopsy site was also identified positively, and the pathologist concluded that the target lesion had been excised with clear margins at directional, vacuum-assisted breast biopsy before wire localization and surgical therapy. No evidence of tumor seeding or epithelial displacement was identified in any of the 36 surgical specimens (13).

DISCUSSION

With use of 14-gauge and 11-gauge directional, vacuum-assisted breast

Table 1

Comparison of 14- and 11-gauge Directional, Vacuum-assisted Probes according to Specimen Weight, Specimen Number, Lesion Diameter, and Percentage of Excisional Biopsies

Probe Size	No. of Biopsies	Average Aggregate Weight (mg)*	Average No. of Specimens Obtained†	Average of Individual Weights per Specimen (mg)‡	Average of Mean Lesion Diameters (mm)‡	Excisional Biopsies (%)§
14	49	1,171	27	44	9.1	59
11	100	1,949	19	105	7.8	79

* Weights were determined in the pathology department. $P \leq .0001$ (unpaired t test).
† $P \leq .0001$ (unpaired t test).
‡ $P \leq .0001$ (unpaired t test).
§ $P \geq .13$ (unpaired t test); no statistically significant difference in measurements.
‖ $P \leq .05$ (unpaired t test).

Table 2

Analysis of Variance of Average Distance off Target according to Count, Mean, Standard Deviation, and Standard Error

Independent Variables	Count	Mean	Standard Deviation	Standard Error
Benign control lesions	22	7.7	3.8	0.8
Deployment method				
13-gauge straight needle	43	12.6	12.3	1.9
11-gauge through probe	106	12.6	7.2	0.7
First imaging follow-up	31	8.7	4.4	0.8

Table 3

Overall Results of Analysis of Variance

	df	Sum of Squares	Mean Square	F Value	*P* Value
Independent variables					
($n = 4$)	3	744	248	3.9	≤.01
Residual	198	12,616	64	...	...

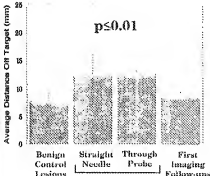


Figure 4. Bar graph shows the plotted average distance off target for each of the four independent variables. Thin bars define the 95% confidence intervals.

biopsies, it is the clinical goal to perform a diagnostic percutaneous breast biopsy as completely and accurately as imaging-guided wire localization and open surgical breast biopsy. With the current directional, vacuum-assisted probes, the goal is not to perform therapeutic breast surgery percutaneously. However, to perform a complete diagnostic breast biopsy, "enough" breast tissue must be obtained percutaneously in all breast lesions. "Enough" tissue may be more tissue than many radiologists are accustomed to removing.

We believe that when stereotactic targeting is nearly perfect, the volume of tissue described in Table 1 for 14-gauge probes is just sufficient to consistently perform a complete and accurate diagnostic breast biopsy. Furthermore, we believe that the volume of tissue obtained with the 11-gauge probe (Table 1) may be sufficient to compensate for small stereotactic targeting errors that occur occasionally. Consequently, we now perform only 11-gauge directional, vacuum-assisted breast biopsies.

Data are available in the literature for atypical ductal hyperplasia and ductal carcinoma in situ lesions that clearly support our first belief. When the diagnosis of atypical ductal hyperplasia is ascertained at percutaneous breast biopsy and surgery is performed subsequently and ductal carcinoma in situ or infiltrating breast cancer is identified at the biopsy site within the surgical specimen, the degree of disease in the breast has been underestimated at percutaneous biopsy (14). Similarly, if ductal carcinoma in situ is identified at percutaneous breast biopsy and infiltrating breast cancer is later identified at surgery, the degree of disease in the breast has been underestimated at percutaneous biopsy (14). When 14-gauge, automated core needle breast biopsies are performed, with acquisition of five to eight specimens per lesion, rates of underestimation of atypical ductal hyperplasia and ductal carcinoma in situ are high, approximately 50% and 20%, respectively (15–17). Even when 17 to 19 specimens are obtained with 14-gauge, automated core needle biopsy, the rate of underestimation of atypical ductal hyperplasia decreases only to 44% and that of ductal carcinoma in situ decreases only to 16% (14).

When 16 or 17 specimens are obtained with 14-gauge, directional vacuum-assisted biopsy, the rate of underestimation of atypical ductal hyperplasia decreases to 18% and the rate of underestimation of ductal carcinoma in situ decreases to 9% (18), (unpublished data). Although these rates are improved compared with rates of underestimation associated with 14-gauge automated core needle biopsies, underestimation of disease at the biopsy site still exists.

To eliminate underestimation of atypical ductal hyperplasia and ductal carcinoma in situ, approximately 30 specimens must be obtained from each lesion with 14-gauge directional, vacuum-assisted biopsy (14). At this level of percutaneous tissue acquisition, over 1 g of tissue is obtained (Table 1). Furthermore, when we use the 11-gauge directional, vacuum-assisted probes, nearly 2 g of tissue are removed at the biopsy site (Table 1).

When over 1 g of tissue is removed from lesions in which the average diameter is 1 cm or less, all mammographic signs of the lesion may be removed as well. If fact, for small lesions (5 mm in diameter or less), we expect to remove all visible signs of the lesion during the directional, vacuum-assisted breast biopsy. The marker clip was developed to ensure that a target would still be present for subsequent wire localization and therapeutic surgery.

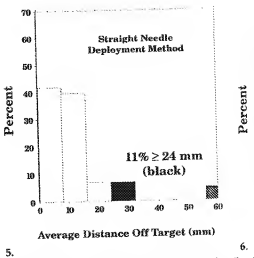
Our study demonstrates that on average, the marker clip was deployed about 5 mm from the center of the target lesion (12.6 mm − 7.7 mm = 4.9 mm). Since the average lesion diameter for the 149 marker clip placements was approximately 10 mm, the overall accuracy of deployment was good. On average, the marker clips were placed just outside the margin of each lesion. Although no clinical problems were encountered from any of the marker clip deployments in our study, there were potential clinically meaningful exceptions to this general rule. In 11% of the straight-needle deployments and 7% of the through-probe deployments, the average distance off target was 24 mm or more. An average distance off target of 24 mm or more could potentially lead to a clinical problem at wire localization and therapeutic surgery. We could not predict from the manipulation of the marker clip deployment system when an off-target deployment had occurred. We were aware of off-target placements only as we examined the two-view mammograms obtained immediately after biopsy.

If the position of the marker clip with respect to the target lesion is known immediately after placement of the marker clip, a deployment error of 24 mm or more would not necessarily lead to a clinical problem. If the position of the marker clip with respect to the target lesion is known, then any error in deployment of the marker clip can be taken into account at wire localization and surgery. However, if the position of the marker clip with respect to the target lesion is not known and the average distance off target is large, then a clinical problem might occur. This clinical problem may occur particularly if the patient underwent stereotactic biopsy and marker clip placement at one site and wire localization and surgery were performed at another. At the second site, it might be assumed incorrectly that the marker clip was exactly on target. Consequently, we believe it is important to document the position of the marker clip after each deployment with a standard two-view, upright mammogram. This two-view upright mammogram should then become a part of the patient record and be available for review before wire localization is performed.

We do not believe it is sufficient to repeat stereotactic mammography while the patient is still on the biopsy table and to use the stereotactic mammogram to measure deployment accuracy. It is possible to calculate the x, y, and z coordinates of the marker clip from a repeat stereotactic mammogram. However, the coordinates calculated may give the operator a false sense of security, since in compression the coordinates of the marker clip are almost always close to the coordinates of the center of the target lesion. Because of the accordion-like character of the breast with bands of tough fibrous tissue alternating with bands of softer, fatty tissue, this method of documenting marker clip position is not reliable. The marker clip may attach to a band of fibrous tissue that in compression is close to the center of the target lesion but when the clip is out of compression it is at some distance from the center of the lesion. To avoid this pitfall, the stereotactic mammograms should be used only to document that the marker clip was deployed. To determine where the marker clip was deployed, upright standard mammography is necessary.

Our study also demonstrates that the marker clip did not change position over the follow-up period of the study (mean, 8.6 months). The average distance off target for marker clip measurements at first imaging follow-up were not statistically significantly different from the average distance off target measurements for the benign control lesions. Therefore, once the location of the marker clip is documented with upright mammography after deployment, it can be safely assumed that the marker clip will remain where deployed for at least 8.6 months. Stability over longer periods has not been documented, to our knowledge.

Marker clip misplacements (average off target distance > 24 mm) were more frequent when the straight-needle deployment method was used than when the through-probe deployment method was used (11% vs 7%, not statistically significant). Furthermore, the straight-needle deployment method necessitated more deployment steps than were necessary for



5. 6.

Figures 5, 6. Graphs show the percentage distribution of the average distance off target for the (5) straight-needle deployment method and the (6) through-probe method. The white bars represent an average distance off target of less than 24 mm; the black bars represent an average distance off target of 24 mm or greater. For the straight-needle deployment method, 11% of the average distance off target measurements were 24 mm or greater, and for the through-probe method, 7% of the average distance off target measurements were 24 mm or greater.

Table 4
Type of Surgery Performed and Histologic Diagnosis in 36 Lesions

Surgery Performed	Metallic Clip Used for Localization	Radiograph Obtained of Surgical Specimen	Histologic Diagnosis			
			Infiltrating Breast Cancer	Ductal Carcinoma In Situ	Atypical Ductal Hyperplasia	Total*
Mastectomy	No	No	4	3	0	7 (19)
Breast conserving	No	No	1	0	0	1 (3)
Breast conserving	Yes	No	6	3	1	10 (28)
Breast conserving	Yes	Yes	9	7	2	18 (50)

* Numbers in parentheses are percentages.

the through-probe method, more time was necessary to perform the straight-needle method because of the greater number of steps, and the straight needle is no longer available from the manufacturer. Consequently, we currently perform only through-probe deployments.

The marker clip was a successful guide for wire localization before surgery. In all 18 cases in which the marker clip was used as a surrogate for the target lesion for wire localization before surgery, the marker clip and the biopsy cavity were identified in each of the 18 surgical specimens.

The mask measurement system for defining the position of the lesion and the marker clip on one image was developed specifically for this study. However, we soon observed that other radiologists who performed wire localization at our center were pulling the masks from the research files at wire localization to analyze the masks before placement of a localization wire. The masks contain all the information necessary to use the marker clip as a reference point at wire localization regardless of whether the marker clip is exactly on target. Consequently, we continue to create a set of masks for each marker clip deployed from mammograms obtained before and after biopsy and marker deployment.

The most common question asked by patients before signing consent for placement of a marker clip was in regard to the size of the clip being placed in the breast. We initially used a small air gap between our thumb and index finger to show marker clip size and informed the patients that the clip was 2 mm. However, this communication method was not very effective, as most patients did not think in terms of millimeters and the space between index finger and thumb was a crude approximation of clip size. To overcome this communication gap, we attached an actual marker clip to an exposed (black) sheet of x-ray film. Against this black background, the marker clip is clearly visible. Once the size of the marker clip was seen, the patients generally expressed no further concern about having the marker clip placed permanently in the breast. We keep the marker clip sample pinned to the wall in the stereotactic breast biopsy room and find it a useful communication aid to obtain informed consent.

Before we used the marker clip, we were able to perform wire localization successfully in all lesions in which stereotactically guided biopsy was performed and surgery was necessary. In small lesions, however, we had a degree of concern with regard to the time between stereotactic biopsy and wire localization. We were particularly concerned when a patient was to be transferred to another facility for wire localization and definitive breast cancer surgery. In the hope that residual blood or air might remain at the biopsy site to identify the biopsy site if the target lesion were removed entirely at stereotactic biopsy, we attempted to minimize the time from stereotactic biopsy to wire localization. This source of concern has now been eliminated. Because of the marker clip, we are now confident that wire localization can be performed successfully at any time after stereotactic breast biopsy whether residual blood or air from the biopsy are present at wire localization.

Finally, with the availability of the marker clip, it is not necessary to place lower size limits on lesions that can undergo stereotactic biopsy. For small lesions (< 5 mm in diameter), we anticipate that in a high percentage of cases all visible signs of the target lesion will be removed. However, because a marker clip is placed after each stereotactic biopsy of these smaller lesions, we are confident that the biopsy site can be reached accurately at wire localization with the marker clip as the surrogate target. Furthermore, even when a marker clip is off target, knowledge of the direction and magnitude of the deployment error allows the marker clip to be used as a clear-cut point of reference for wire localization. ■

References

1. Pisano ED, Tsimikas J, Fajardo L, et al. RDOG5: stereotactic fine needle aspiration (FNA) and core needle biopsy (CNB) in the work-up of lesions detected by mammography—insufficiency sample rate across multiple centers in a nationwide trial. Presented at the 27th National Conference on Breast Cancer, Dallas, Tex, 1996.
2. Parker SH, Lovin JD, Jobe WE, et al. Stereotactic breast biopsy with a biopsy gun. Radiology 1990; 176:741–747.
3. Dershaw DD. Needle core biopsy of mammographic lesions (letter). AJR 1995; 164:260.
4. Sullivan DC. Needle core biopsy of mammographic lesions (letter). AJR 1994; 162: 601–608.
5. Dronkers DJ. Stereotaxic core biopsy of breast lesions. Radiology 1992; 183:631–634.
6. Mikhail RA, Nathan AC, Weiss M, et al. Stereotactic core needle biopsy of mammographic breast lesions as a viable alternative to surgical biopsy. Ann Surg Oncol 1994; 1:363–367.
7. Burbank F, Parker SH, Fogarty TJ. Stereotactic breast biopsy: improved tissue harvesting with the Mammotome. Am Surg 1996; 62:128–150.
8. Burbank F. Mammographic findings after 14-gauge automated needle and 14-gauge directional vacuum-assisted stereotactic breast biopsy. Radiology 1997; 204:153–156.
9. Burbank F. Frequency of excisional breast biopsy with clear margins with the Biopsys Mammotome (abstr). Mini Invasive Ther Allied Technol 1996; 5(suppl):39.
10. Burbank F. Stereotactic breast biopsy: comparison of 14- and 11-gauge Mammotome probe performance and complication rates. Am Surg 1997 (in press).
11. Burbank F. Stereotactic breast biopsy: its history, its present, and its future. Am Surg 1996; 62:128–150.
12. American College of Radiology (ACR). Breast Imaging Reporting and Data System (BI-RADS). 2nd ed. Reston, Va: American College of Radiology, 1995.
13. Youngson BJ, Cranor M, Rosen PP. Epithelial displacement in surgical breast specimens following needling procedures. Am J Surg Pathol 1994; 18:896–903.
14. Burbank F. Stereotactic breast biopsy of atypical ductal hyperplasia and ductal carcinoma in situ lesions: improved accuracy with a directional, vacuum-assisted biopsy instrument. Radiology 1997; 202:843–847.
15. Jackman RJ, Nowels KW, Shepard MJ, Finkelstein SI, Marzoni FA. Stereotaxic large-core needle biopsy of 450 nonpalpable breast lesions with surgical correlation in lesions with cancer or atypical hyperplasia. Radiology 1994; 193:91–95.
16. Liberman L, Cohen MA, Dershaw DD, Abramson AF, Hann LE, Rosen PP. Atypical ductal hyperplasia diagnosed at stereotaxic core biopsy of breast lesions: an indication for surgical biopsy. AJR 1995; 164: 1111–1113.
17. Liberman L, Dershaw DD, Rosen PP, et al. Stereotaxic core biopsy of breast carcinoma: accuracy at predicting invasion. Radiology 1995; 194:379–381.
18. Jackman RJ, Burbank F, Parker SH, et al. Atypical ductal hyperplasia diagnosed with stereotactic biopsy: improved reliability with 14-gauge, directional vacuum-assisted breast biopsy. Radiology 1997; 204: 485–488.